Aortic Customize: A new alternative endovascular approach to aortic aneurysm repair using injectable biocompatible elastomer. An in vitro study

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Purpose: **Aortic Customize is a new concept for endovascular aortic aneurysm repair in which a non polymerized elastomer is injected to fill the aneurysm sac around a balloon catheter. The aim of this in vitro study was to investigate the extent of aneurysm wall stress reduction by the presence of a noncompliant elastomer cuff.**

Methods: **A thin-walled latex aneurysm (inner radius sac 18 mm, inner radius neck 8 mm), equipped with 12 tantalum markers, was attached to an in vitro circulation model. Fluoroscopic roentgenographic stereo photogrammetric analysis (FRSA) was used to measure marker movement during six cardiac cycles. The radius of three circles drawn through the markers was measured before and after sac filling. Wall movement was measured at different systemic pressures. Wall stress was calculated from the measured radius ($\sigma = pr/2t$).**

Results: **The calculated wall stress was 7.5-15.6 N/cm^2 before sac filling and was diminished to 0.43-1.1 N/cm^2 after sac filling. Before sac filling, there was a clear increase ($P < .001$) in radius of the proximal (range, 7.9%-33.5%), middle (range, 3.3%-25.2%), and distal (range, 10.5%-184.3%) rings with increasing systemic pressure. After sac filling with the elastomer, there remained a small, significant ($P < .001$) increase in the radius of the circles (ranges: 6.8%-8.8%; 0.7%-1.1%; 5.3%-6.7%). The sac filling reduced the extent of radius increase. The treated aneurysm withstood systemic pressures up to 220/140 mm Hg without noticeable wall movement. After the sac filling, there was no pulsation visible in the aneurysm wall.**

Conclusions: **Filling the aneurysm sac of a simplified in vitro latex model with a biocompatible elastomer leads to successful exclusion of the aneurysm sac from the circulation. Wall movement and calculated wall stress are diminished noticeably by the injection of biocompatible elastomer. (J Vasc Surg 2010;51:1230-7.)**

Clinical Relevance: **Filling the aneurysm sac with an elastomer has a lot of potential advantages, compared with the current endovascular treatment options. To fill the sac with the biocompatible elastomer, only a fill catheter with diameter of minimal 7 F and endovascular balloons need to be introduced transfemorally to the aneurysm sac. Most stent grafts need a minimal diameter of 14 F-22 F for access to the bulky delivery sheath, which makes many aneurysms with strong tortuosity or occlusive disease of the iliac arteries ineligible for treatment. In theory, any abdominal aortic aneurysm with a deviant anatomy will become treatable, as endovascular balloons will be available in different kinds of shape and configurations. As stated above, future research must take place before this treatment option can be applied in vivo. Animal experiments will take place to prevent embolic complications during the filling process and to investigate the short- and long-term effects of the presence of the elastomer in the aorta. Research on this novel treatment concept is in full progress and will be reported in the near future.**

Endovascular aortic aneurysm repair (EVAR) has become a well-established treatment of abdominal aortic aneurysms (AAAs). Mortality after EVAR is significantly reduced compared with open repair.[1,2] Despite these successes, EVAR has several drawbacks.

Complications and reinterventions caused mainly by endoleaks, endotension, stent graft migration, and device failure are of major concern.[3,4] Lifelong follow-up is therefore needed because these complications can be associated with aneurysm rupture. Furthermore, EVAR

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Drs de Vries, Brom, and Jacobs have developed and patented the elastomer used in the experiment. The other authors have no financial or other competing interests in the experiments.

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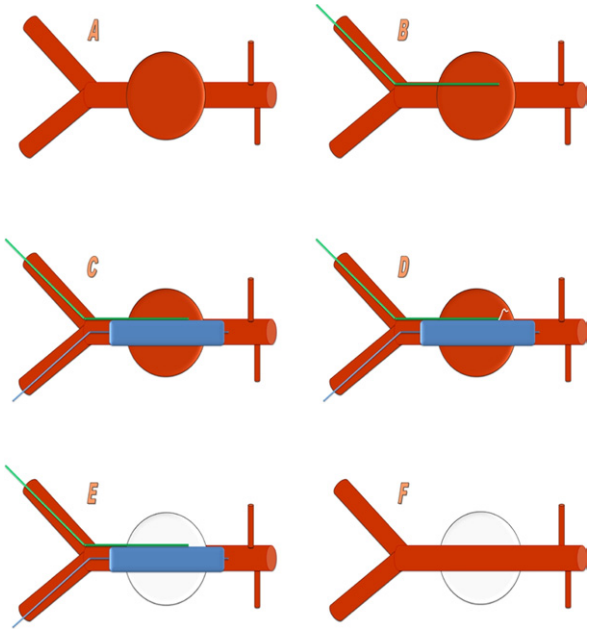

Fig 1. Aortic Customize, the treatment concept. **A.** A schematic drawing of an abdominal aortic aneurysm. **B.** A fill catheter is inserted through a femoral artery. **C.** An endovascular balloon excludes the aneurysm from the circulation. **D.** The two components of the elastomer are pumped in the excluded aneurysm. Excess blood is pushed out alongside the balloon. **E.** After the aneurysm is filled, the elastomer takes five minutes to cure. **F.** When the elastomer has cured, the endovascular balloon is deflated, leaving the aneurysm excluded with a new lumen.

has anatomical restrictions. Manufacturers of commercial available EVAR grafts state that an infrarenal aneurysm neck of at least 15 mm is needed to ensure a strong proximal seal, and tortuous anatomy is a (relative) contraindication. Timaran et al have shown that with 27% of AAAs, the anatomy of the aneurysm makes it unsuitable for EVAR because of insufficient neck length, large neck diameter, or severe angulation.[5]

To overcome these disadvantages, Aortic Customize was devised: a method of excluding the infrarenal aortic aneurysm using endovascular techniques to inject a biocompatible elastomer into the aneurysm sac (Fig 1). The nonpolymerized liquid elastomeric solution is used to fill the aneurysm sac around a balloon catheter. An endoluminal mold obliterates the aneurysm sac after in situ polymerization. After balloon deflation, a noncompliant elastomer cuff with a patent lumen is created.

Filling the aneurysm sac with an injectable biocompatible elastomer will realize a reduction in the wall stress and thereby a reduction in rupture risk, since aneurysm rupture occurs when the local wall stress exceeds the local wall strength.[6,7]

The aim of this in vitro study is to measure the influence of aneurysm sac exclusion by an injectable biocompatible elastomer on the aneurysm wall motion and thereby on the aneurysm wall stress.

Our hypothesis is that exclusion with an elastomer cuff will reduce wall motion. This will, in combination with the augmentation of the aneurysmal wall, lead to a reduction of the aneurysmal wall stress.

MATERIALS AND METHODS

Setup. An in vitro circulation model (Fig 2), validated and described previously, was used.[8] A plexiglass box containing a latex aneurysm was connected to the in vitro circulation model.

Systemic pressures were measured by a Datascope 2000 digital pressure monitor (Datascope Corporation, Paramus, NJ).

Latex aneurysm models. In this experiment, a thin-walled fusiform latex aneurysm model (AAA) was used. The maximum inner radius of the aneurysm was 18.25 mm and the inner radius of the proximal and distal aorta, 8 mm. The latex aneurysm wall was 0.8 mm thick. Twelve tantalum markers (Ø0.8 mm) (M1-12) were placed in the latex wall (Fig 3) for fluoroscopic roentgenographic stereo photogrammetric analysis (FRSA) measurements. The markers were placed in three planes of four markers on the proximal (M1-4) and distal neck (M9-12) and on the middle (widest) part (M5-8) of the AAA.

Compliance of aneurysm. The compliance (C) of the latex aneurysm was calculated by measuring the volume (δV) needed to obtain a pressure increase (δP) in the isolated aneurysm as $C = \delta V/\delta P$.[9] The compliance was measured in the pressure region 30 mm Hg-160 mm Hg.

FRSA setup. Wall motion (mm) of the aneurysm wall was measured by using fluoroscopic roentgenographic stereo photogrammetric analysis.[10] FRSA is performed by calculating the point of intersection of two projection lines of a marker in space by using calibrated stereo roentgenographic imaging (Fig 2).[10-14] A Siemens Axiom Artis dBc imaging system (Siemens AG, Erlangen, Germany), which consists of two C-arms with digital flat panel Roentgen detectors (1024 × 1024 pixels, 14 bits grey scale resolution, 30 images/second) was used to acquire the roentgen images. The focus to detector distance was set at 100 cm. The two C-arms were positioned at a 90 degree angle, to produce a posterior-anterior image and a lateral image. The image pairs were analyzed by using model-based RSA software (ModelBased-RSA 3.21; MEDIS Specials, Leiden, The Netherlands) to calculate the relative three-dimensional marker positions.[10,12,13] FRSA has an accuracy of 0.003 mm ± 0.0019 mm on marker motion detection.[10]

The elastomer. We used a low-viscous elastomer, polydimethylsiloxane (PDMS; ViaZym BV, Delft, The Netherlands). PDMS is a silicone rubber composed of two components. It is widely used in vivo because of its physiological inert properties.[15-17] PDMS has also been used in different types of vascular grafts, as a method to increase the sealing of the material and to decrease the platelet adhesion to the graft material. PDMS has proven in several studies to increase hemocompatibility when compared with materials currently used in vascular grafts.[18-20] PDMS cures without

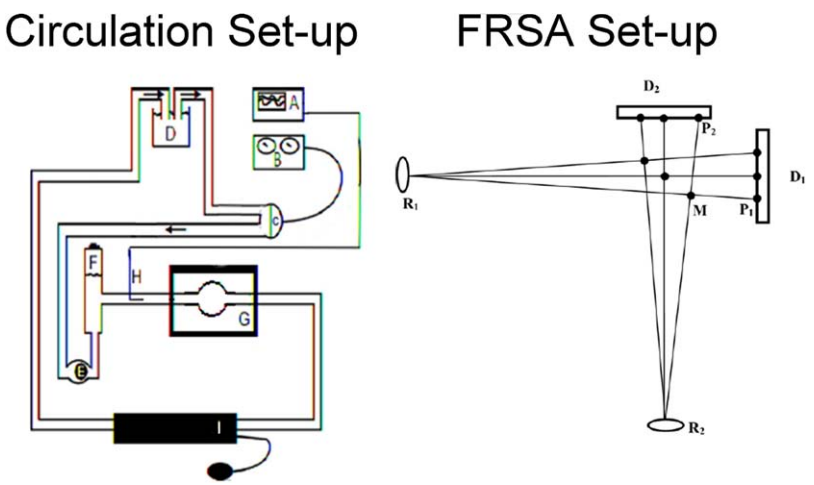

Fig 2. A schematic representation of the circulation setup and the FRSA setup. The circulation setup consisted of a pressure measuring device **(A)**, an artificial heart driver **(B)**, left ventricle **(C)**, an open reservoir **(D)**, a ball valve **(E)**, an air-chamber **(F)**, an air-tight pressure box with a latex aneurysm **(G)**, a systemic pressure sensor **(H)**, and a blood pressure cuff **(I)**. The FRSA setup consisted of the roentgen foci (R1 and R2), the detectors (D1 and D2). Their relative positions are known by calibration of the setup. Markers give projections P1 and P2 on the detectors. With a calibrated setup, projection lines can be reconstructed. Calculation of intersections M of these projection lines in space gives the positions of the markers. *FRSA,* Fluoroscopic roentgenographic stereo photogrammetric analysis.

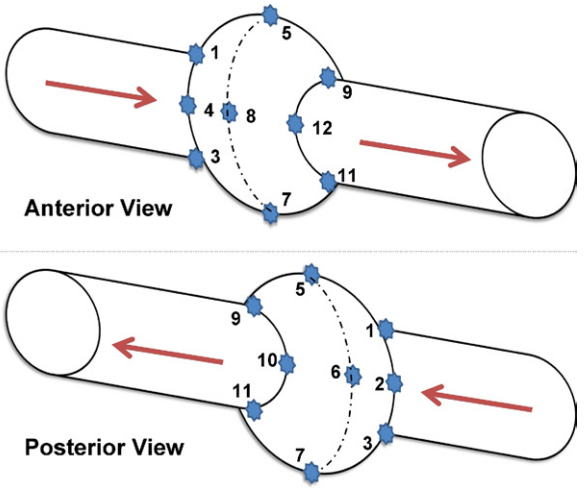

Fig 3. The latex aneurysm (length 37.5 mm; widest Ø 36.5 mm; neck Ø 16 mm) was equipped with 12 tantalum markers (Ø 0.8 mm). The markers were placed in three circles of four markers (1-4) at respectively the proximal neck (1-4), the middle part (5-8), and the distal neck (9-12). The arrows indicate the direction of the circulation.

exothermic heat; there is no release or formation of by-products as it hardens (polymerization and cross-linking) in a watery environment at 37°C.

Method of excluding the aneurysm. The latex aneurysm was connected to the circulation model. The lumen of the AAA was excluded by inflating an Ø 8-mm and 60-mm long endovascular balloon (Cordis Corporation, New Brunswick, NJ). The AAA was punctured with an 8-gauge vertebroplasty needle (Biomet Inc, Warsaw, Ind) and a 19-gauge needle. A static mixer and the two-component elastomer canister were connected to the 8-gauge needle. The 19-gauge needle was left open as a poassible exit of the liquid, present in the aneurysm sac. The aneurysm was filled with the biocompatible elastomer and was considered full when elastomer leaked out of the 19-gauge exit needle. Curing of the elastomer took place in five minutes, leaving a firm mass in the aneurysm sac. The endovascular balloon was deflated, leaving a lumen in the cured elastomer.

In the absence of a clotting system, a tie-rap was applied to prevent dissection between the elastomer and the latex aneurysm on both sides of the aneurysm.

Measurements. The movement of the markers was measured in each of the aneurysms before and after excluding the aneurysm with the biocompatible elastomer. Through the markers, three circles were fitted using routines, implemented in Matlab r2006B (The Mathworks, Natrick, Mass; Fig 3): a proximal ring (M1-4), a middle ring (M5-8), and a distal ring (M9-12).

Wall stress (σ) [N/cm^2] was calculated using the following formula:[21]

$$\sigma = \frac{pr}{2t}$$

The systolic, diastolic, and mean pressure (p; n/cm^2; 1 mm Hg = 0.0133 N/cm^2) were known from the pressure measurements, the radius (r; cm) was calculated from the FRSA measurements, and the thickness of the aneurysm (t) was known from fabrication (0.08 cm) and was considered constant during the experiment.

Table I. Increase of radius of the aneurysm sac

	Proximal ring		*Middle ring*		*Distal ring*	
	r (mm)	*%*	*r (mm)*	*%*	*r (mm)*	*%*
Before						
60/40 mm Hg	0.7	7.8	0.6	3.3	0.9	10.5
80/60 mm Hg	2.9	33.5	2.5	13.3	3.8	43.4
90/60 mm Hg	1.8	20.2	4.8	25.2	16.1	184.3
After						
90/60 mm Hg	0.6	7.1	0.1	0.7	0.5	5.3
120/80 mm Hg	0.7	7.6	0.1	0.8	0.5	5.6
150/100 mm Hg	0.6	6.8	0.1	0.7	0.5	5.2
220/140 mm Hg	0.8	8.8	0.2	1.1	0.6	6.7

The marker movement was measured with different pressure settings: 60/40, 80/60, 90/60, 120/80, 150/100, and 220/140 mm Hg. The circulation pump ran on a frequency of 70 bpm.

Statistics. The results were analyzed with the statistics program SPSS 16.0 for Windows (SPSS Inc, Chicago, Ill). Linear regression models with mean pressure (mm Hg) as predictor and radius (mm) as outcome were used to analyze the wall movement before and after the injection of the biocompatible elastomer. The slope (b) of the regression model was compared for each ring before and after sac filling.

RESULTS

Compliance. The mean compliance of the aneurysm was 0.41 mL/mm Hg (0.15 mL/mm Hg-0.91 mL/mm Hg) in the pressure range of 30 mm Hg-90 mm Hg. The thin-walled aneurysm nearly ruptured at pressures higher than 90 mm Hg, as wall stress nearly exceeded wall strength. Therefore, only compliance data from lower than 90 mm Hg were available. In the circulation setup, we were only able to measure the wall movement up to a pressure of 90/60 mm Hg (MAP 70 mm Hg) before treatment, as the aneurysm nearly ruptured at higher pressures.

Radius. The FRSA measurements before sac filling showed a clear increase in average radius of the proximal, middle, and distal rings (3.3%-184.3%; Table I) with increasing systemic pressure. After sac filling with the elastomer, there was little change in the radius of the circles (0.7%-8.8%; Table I).

Linear regression models showed a significant increase in radius of the rings as a result of systematic pressure before sac filling (Table II and Fig 4).

After treatment with the elastomer, the increase in the radius of the circles declined to almost zero but remained significant (Table II and Fig 4). There was minimal-to-zero marker movement as pulsatility disappeared from the treated aneurysm (Fig 5).

Wall stress. Wall stress calculations showed that before sac filling, the wall stress ranged from 7.5-13.3 N/cm^2, while after sac filling, the wall stress was diminished to 0.5-1.2 N/cm^2 (Fig 4).

Table II. Results of the linear regression model

	Before treatment		*After treatment*	
	Slope (mm/mm Hg)	P	*Slope (mm/mm Hg)*	P
Proximal ring (M1-4)	0.099	<.001	0.001	<.001
Middle ring (M5-8)	0.112	<.001	0.001	<.001
Distal ring (M9-12)	0.245	<.001	0.001	<.001

DISCUSSION

This study clearly demonstrates that filling an AAA sac of a simplified in vitro latex model with an elastomer results in a decrease of wall stress (Fig 4). After sac filling, there was nearly no wall movement, not even with a pressure of ±220/140 mm Hg (Fig 6).

Wall stress on the latex aneurysm was diminished as the radius did not increase, and the wall thickness was increased due to filling of the aneurysm sac from 0.8 mm to 18 mm at the middle ring. Calculations showed that the wall stress declined from 7.5-13.3 N/cm^2 to 0.5-1.2 N/cm^2 after sac filling. It should be noted that these values are rough estimates, as they are calculated from the mean arterial pressure, the measured radius, and wall thickness. During the experiments before treatment at a pressure of 90/60 mm Hg, the local wall strength was exceeded at the site of the distal ring, leading to a rapid expansion of ±190% of its original size. This led to a pressure fall in the remaining aneurysm sac, which led to a decrease in the radius of the proximal ring (Fig 4). The slope of the linear regression model of the proximal ring of the untreated aneurysm is therefore remarkably lower than the slope of the middle and distal ring (Table I).

In the untreated aneurysm models, there was a large spread in measurements, which was due to the pulsatility of the aneurysm. After sac filling, the spread is narrow as the elastomer absorbs the pulse waves (Figs 4 and 5).

The linear regression models show that before and after sac filling there is a statistically significant increase in wall

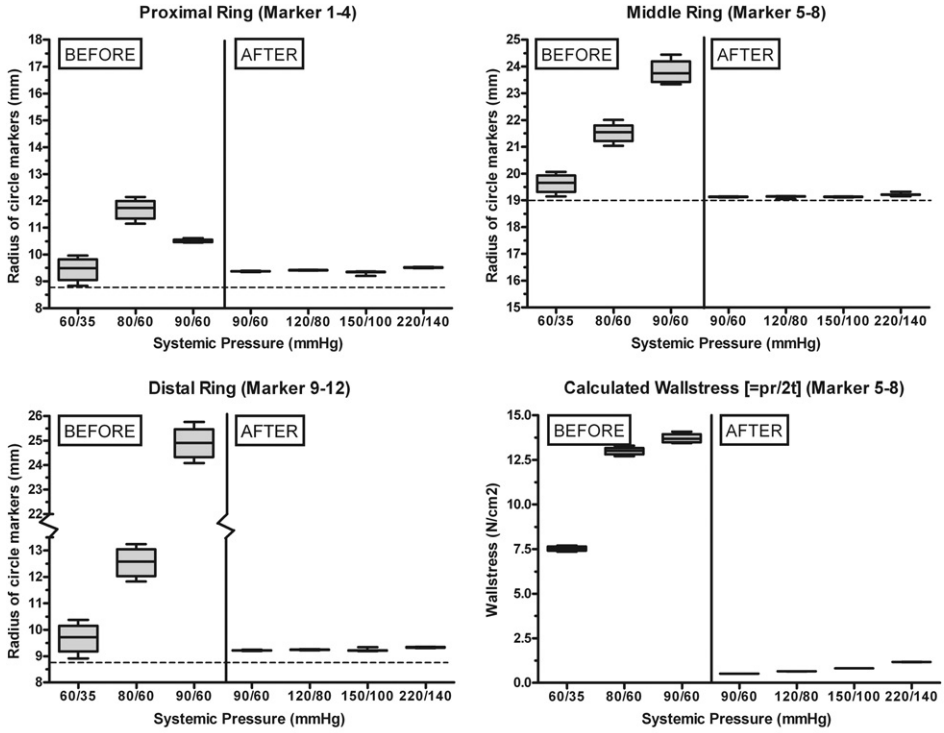

Fig 4. The radius of the three circles drawn through the markers as a result of the systemic pressure before and after sac filling with the elastomer. The dotted lines show the original outer radius (19 mm and 8.75 mm) of the latex aneurysm on the ring positions. The inset shows the wall stress as it was calculated from the mean arterial pressure (p), the radius of the middle ring of the aneurysm sac (r), and the wall thickness (t) ($\sigma = pr/2t$).

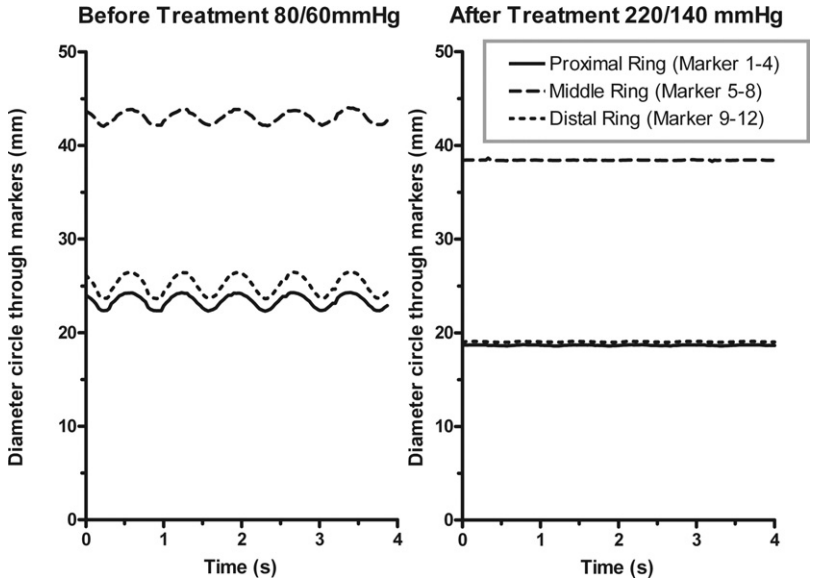

Fig 5. The diameter of circles drawn through the marker rings. The left graph shows the movement of the markers before elastomer injection at a pressure of 80/60 mm Hg. The right graph shows the movement of the markers after elastomer injection at a pressure of 220/140 mm Hg.

radius due to an increase in the systemic pressure (Table II). However, the slopes of the models should be compared before and after sac filling. The linear regression models after sac filling show a slope of 0.001 mm/mm Hg, which is a nearly horizontal line (Table II). This means that with a mean pressure increase of 100 mm Hg, the radius of the

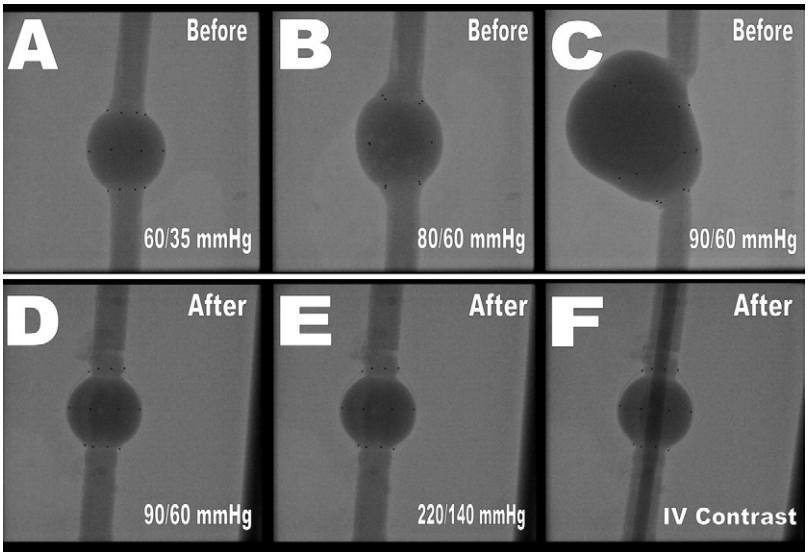

Fig 6. An overview of maximal dilation of the latex aneurysm during systole. The angiographies **A**-**C** are recordings before elastomer injection, **D**-**F** after elastomer injection. The systemic pressure at time of the recording is noted in the right lower quadrant. Massive dilatation is visible with increasing pressures in the recordings **A**-**C**, while there is no dilation at higher pressures in recordings **D**-**E**. Recording **F** shows a patent lumen when contrast is added to the perfusion solution. The 12 black dots visible on each aneurysm are the tantalum markers.

aneurysm sac only increases 0.1 mm. The slopes of the model before sac filling are noticeably higher, as can be seen in Table II and Fig 4.

The in vitro experiment shows the large potential of this new treatment concept. We appreciate the fact that every in vitro experiment is a simplification of the in vivo situation. The anatomy of the used aneurysm is simple, making its exclusion easy. The "aneurysmal wall" was made of latex and differs clearly from the in vivo situation, whereby there is a high amount of intraluminal thrombus and other degenerative processes. However, the use of in vitro circulation models with latex aneurysms is, in spite of its limitations, a broadly accepted method to investigate physiological questions concerning aneurysm repair.[9,22-25]

For this experiment, we opted for direct injection in the aneurysm sac through a needle for practical reasons. The elastomer was pumped easily through the fill needle, filled the excluded aneurysm easily, leaving a perfect mould of the latex AAA with a straight patent lumen at the place of the balloon (Fig 7). Other, still unpublished, in vitro experiments have shown to us that the elastomer can be pumped easily with a flow rate of 1.15 mL/s through a 7 F catheter up to a length of 90 cm, opening all kind of possibilities for applications by percutaneous catheter applications.

Another shortcoming might be the fact that we used the measured wall motion and the mean pressure to calculate the wall stress (σ). We used the formula $\sigma = pr/2t$, as the sac of the latex aneurysm resembled a sphere. The radius was only known on the site of the markers. However, local wall stress could be higher or lower on different sites of the aneurysm. We chose to use this method as it was accurate and easy in use, while other, more complicated methods such as infinite model stress analysis[26] were not available to us, and other methods with fixed-strain gauges are not very sensitive and may influence the measurements.[27] As this study was setup as a proof-of-principle-experiment, we were satisfied with approximations of wall stress on a few sites of the aneurysm sac. The important finding is the difference in wall stress, before and after sac filling (Fig 4).

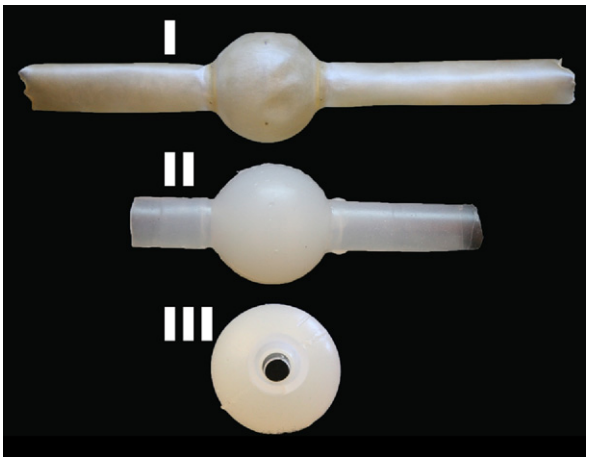

Fig 7. The latex aneurysm with the tantalum markers **(I)**. After the curing of the elastomer, a cast of the aneurysm sac is formed **(II)**, leaving a silicone-reinforced artery with a patent lumen **(III)**.

Potential limitations of treatment method. Before this technique can be used in vivo, a few hurdles have to be

taken. For the concept to work in vivo, a blood- and pressure-tight seal is preferable. In this in vitro model, the seal was obtained by applying a tie rap on the outer side of the latex aneurysm. In vivo, this potential cause of type I endoleaks can be treated by placing a Palmaz stent, fixating the elastomer to the vessel wall.

When working with arterial embolic agents, there is always the risk of developing an embolus. An embolus in the lumbar arteries or in the inferior mesenteric artery might lead to paraplegia or colonic ischemia. However, we expect that the elastomer will not travel far in the inferior mesenteric artery or lumbar arteries. In our extensive studies with the in vitro model, emboli were not noted. The elastomer is more viscous and heavier then blood. The elastomer will press the blood out of the sac as it fills up the AAA. Due to the smaller diameter of the arteries, there will be a higher pressure in the side branches. Therefore, the side branches will fill up when the whole sac is filled. At that moment, the curing process of the elastomer is in full progress, the substance becomes even more viscous, and it will be very difficult for it to travel far in a pressurized small-diameter vessel. Furthermore, it should be noted that with the current EVAR treatment of infrarenal AAAs, by which the inferior mesenteric artery is excluded as well, complications such as colon ischemia are seldom seen.

In nonthrombosed large infrarenal aneurysms, the needed volume of elastomer can be up to 400 mL-500 mL. Theoretically, this might cause shear forces at the borders of the native aorta/common iliac arteries and the elastomer lump and might increase the risk of kinking and obstruction. However, we do not expect this to happen. The density of blood and thrombus is respectively 1.05 g/cm^3 and 1.09 g/cm^3. The density of our elastomer is 1.0167 g/cm^3. This density is less than the density of blood and thrombus. The shear forces at the borders of the native aorta before and after treatment with the elastomer should be in the same range. Hence, we do not believe that the risk of kinking will increase.

All the potential shortcomings and their potential solutions remain speculation. Before in vivo application, animal experiments must be done to see if these complications occur and how they can be treated at best.

To our knowledge, this report is the first to describe the novel aneurysm treatment technique, and no similar technique has been described in the literature. There has been word of an endoluminal stent graft called "the Nellix-Sac," where the system is fixated in the aneurysm by filling a sac, which is incorporated in the graft, with a polymer. However, there has been no scientific article published about the treatment concept.

CONCLUSIONS

Filling the aneurysm sac with a biocompatible elastomer may lead to successful exclusion of the aneurysm sac from the circulation. Wall movement and the consequent wall stress are diminished by the injection of biocompatible elastomer.

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AUTHOR CONTRIBUTIONS

Conception and design: WB, TS, JWH, BK, AV, HB, MJ, JFH
Analysis and interpretation: WB, TS, JWH, BK
Data collection: WB, TS, JWH, BK
Writing the article: WB
Critical revision of the article: TS, JWH, BK, AV, HB, MJ, JFH
Final approval of the article: TS, JWH, BK, AV, HB, MJ, JFH
Statistical analysis: WB
Obtained funding: JFH
Overall responsibility: WB, TS, JFH

REFERENCES

1. Prinssen M, Verhoeven EL, Buth J, Cuypers PW, van Sambeek MR, Balm R, et al. A randomized trial comparing conventional and endovascular repair of abdominal aortic aneurysms. N Engl J Med 2004;351:1607-18.
2. Greenhalgh RM, Brown LC, Kwong GP, Powell JT, Thompson SG. Comparison of endovascular aneurysm repair with open repair in patients with abdominal aortic aneurysm (EVAR trial 1), 30-day operative mortality results: randomised controlled trial. Lancet 2004;364:843-8.
3. Kelso RL, Lyden SP, Butler B, Greenberg RK, Eagleton MJ, Clair DG. Late conversion of aortic stent grafts. J Vasc Surg 2009;49:589-95.
4. Bell PR. Randomised trials EVAR and clinical practice. J Cardiovasc Surg (Torino) 2006;47:61-4.
5. Timaran CH, Rosero EB, Smith ST, Modrall JG, Valentine RJ, Clagett GP. Influence of age, aneurysm size, and patient fitness on suitability for endovascular aortic aneurysm repair. Ann Vasc Surg 2008;22:730-5.
6. Vorp DA, Raghavan ML, Webster MW. Mechanical wall stress in abdominal aortic aneurysm: influence of diameter and asymmetry. J Vasc Surg 1998;27:632-9.
7. Vorp DA, Raghavan ML, Muluk SC, Makaroun MS, Steed DL, Shapiro R, et al. Wall strength and stiffness of aneurysmal and nonaneurysmal abdominal aorta. Ann N Y Acad Sci 1996;800:274-6.
8. Hinnen JW, Visser MJ, Schurink GW, Hamming JF, van Bockel JH. Validation of an in vitro model of the human systemic circulation for abdominal aortic aneurysm-studies. In: Hinnen JW, editor. Pitfalls of aneurysm sac pressure monitoring. Leiden: Leiden University, 2007. p. 35-50.
9. Bosman WM, Hinnen JW, Rixen DJ, Hamming JF. Effect of stent-graft compliance on endotension after EVAR. J Endovasc Ther 2009;16:105-13.
10. Koning OH, Kaptein BL, Garling EH, Hinnen JW, Hamming JF, Valstar ER, et al. Assessment of three-dimensional stent-graft dynamics by using fluoroscopic roentgenographic stereophotogrammetric analysis. J Vasc Surg 2007;46:773-9.
11. Koning OH, Garling EH, Hinnen JW, Kroft LJ, van der Linden E, Hamming JF, et al. Accurate detection of stent-graft migration in a pulsatile aortic model using Roentgen stereophotogrammetric analysis. J Endovasc Ther 2007;14:30-8.

12. Vrooman HA, Valstar ER, Brand GJ, Admiraal DR, Rozing PM, Reiber JH. Fast and accurate automated measurements in digitized stereophotogrammetric radiographs. J Biomech 1998;31:491-8.
13. Kaptein BL, Valstar ER, Stoel BC, Rozing PM, Reiber JH. A new model-based RSA method validated using CAD models and models from reversed engineering. J Biomech 2003;36:873-82.
14. Koning OH, Oudegeest OR, Valstar ER, Garling EH, van der Linden E, Hinnen JW, et al. Roentgen stereophotogrammetric analysis: an accurate tool to assess stent-graft migration. J Endovasc Ther 2006;13: 468-75.
15. Kheir JN, Leslie LF, Fulmer NL, Edlich RF, Gampper TJ. Polydimethylsiloxane for augmentation of the chin, malar, and nasal bones. J Long Term Eff Med Implants 1998;8:55-67.
16. Arkles B. Look what you can make out of silicones. Chemtech 1983; 13:542-55.
17. van der Steenhoven TJ, Schaasberg W, de Vries AC, Valstar ER, Nelissen RG. Augmentation with silicone stabilizes proximal femur fractures: an in vitro biomechanical study. Clin Biomech (Bristol, Avon) 2009;24:286-90.
18. Spiller D, Losi P, Briganti E, Sbrana S, Kull S, Martinelli I, et al. PDMS content affects in vitro hemocompatibility of synthetic vascular grafts. J Mater Sci Mater Med 2007;18:1097-104.
19. Lumsden AB, Chen C, Coyle KA, Ofenloch JC, Wang JH, Yasuda HK, et al. Nonporous silicone polymer coating of expanded polytetrafluoroethylene grafts reduces graft neointimal hyperplasia in dog and baboon models. J Vasc Surg 1996;24:825-33.
20. Larena-Avellaneda A, Dittmann G, Haacke C, Graunke F, Siegel R, Dietz UA, et al. Silicone-based vascular prosthesis: assessment of the mechanical properties. Ann Vasc Surg 2008;22:106-14.
21. Raghavan ML, Kratzberg JA, Golzarian J. Introduction to biomechanics related to endovascular repair of abdominal aortic aneurysm. Tech Vasc Interv Radiol 2005;8:50-5.
22. Hinnen JW, Koning OH, Vlaanderen E, van Bockel JH, Hamming JF. Aneurysm sac pressure monitoring: effect of pulsatile motion of the pressure sensor on the interpretation of measurements. J Endovasc Ther 2006;13:145-51.
23. Gawenda M, Heckenkamp J, Zaehringer M, Brunkwall J. Intra-aneurysm sac pressure–the holy grail of endoluminal grafting of AAA. Eur J Vasc Endovasc Surg 2002;24:139-45.
24. Gawenda M, Knez P, Winter S, Jaschke G, Wassmer G, Schmitz-Rixen T, et al. Endotension is influenced by wall compliance in a latex aneurysm model. Eur J Vasc Endovasc Surg 2004;27:45-50.
25. Hinnen JW, Koning OH, Visser MJ, Van Bockel HJ. Effect of intraluminal thrombus on pressure transmission in the abdominal aortic aneurysm. J Vasc Surg 2005;42:1176-82.
26. Fillinger MF, Raghavan ML, Marra SP, Cronenwett JL, Kennedy FE. In vivo analysis of mechanical wall stress and abdominal aortic aneurysm rupture risk. J Vasc Surg 2002;36:589-97.
27. Flora HS, Talei-Faz B, Ansdell L, Chaloner EJ, Sweeny A, Grass A, et al. Aneurysm wall stress and tendency to rupture are features of physical wall properties: an experimental study. J Endovasc Ther 2002;9:665-75.

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